

AUG 22 2005

Summary  
K051841

## **510(k) SUMMARY**

Date of Summary: August 2, 2005

### **Product Name:**

WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test

### **Sponsor and Manufacturer**

WHPM, Inc.

9440 Telstar Avenue, Unit 1

El Monte, CA 91731

### **Correspondent**

Fran White, President

MDC Associates, LLC

163 Cabot Street

Beverly, MA 01915

### **Substantially Equivalent Devices**

Manufacturer: Acon Laboratories

Product: One Step Pregnancy Test (Urine/Serum) [510(k) number: K993065]

### **Product Description**

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a lateral flow immunoassay intended for the detection of human Chorionic Gonadotropin (hCG) in urine or serum.

### **Intended Use**

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

### **Summary of Technology**

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test employs a unique combination of monoclonal-dye conjugate and polyclonal solid-phase antibodies to selectively identify human Chorionic Gonadotropin (hCG) in urine and serum. As the urine or serum sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band if hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no line in the reaction zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

### **Performance Data**

A method comparison study was done to compare the performance of the WH Accu

Test™ Pregnancy Test. These data clearly demonstrate the performance of the product manufactured by WHPM is substantially equivalent to the Acon Laboratories hCG One Step Pregnancy Test (Urine/Serum). 100% agreement was observed.

Agreement = 100%

**Statement of Safety and Efficacy**

The WH Accu Test™ One Step Pregnancy Test when compared with another commonly used pregnancy test (Acon Laboratories hCG One Step Pregnancy Test) demonstrated 100% performance.

These data clearly demonstrate the safety and efficacy of the WH Accu Test™ One Step Pregnancy Test and further confirms the accuracy of the product when compared to a substantially equivalent device currently being sold for professional use. Testing was done by a person who routinely performs pregnancy tests.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WHPM, Inc.  
c/o Ms. Fran White  
Regulatory Consultant  
MDC Associates, LLC  
163 Cabot Street  
Beverly, Massachusetts 01915

AUG 22 2005

Re: k051841  
Trade/Device Name: WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test  
Regulation Number: 21 CFR § 862.1155  
Regulation Name: Human chorionic gonadotropin test system  
Regulatory Class: II  
Product Code: JHI  
Dated: August 4, 2005  
Received: August 5, 2005

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

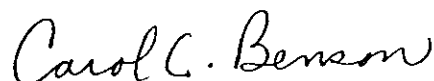
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Carol C. Benson". The signature is written in a cursive, flowing style.

Carol C. Benson, M.A.  
Acting Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051841/S<sup>1</sup>

Device Name: WH AccuTest One Step Urine/Serum Combo Pregnancy Test

### Indications For Use:

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of GDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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